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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,421	02/26/2002	Koji Hanasaki	2002-0287A	3293

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EXAMINER	
FORD, JOHN M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,421	HANASAKI ET AL.	
	Examiner	Art Unit	
	John M Ford	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1--7, 15--23 and 28--44* is/are pending in the application.

4a) Of the above claim(s) *1--7, 15--23 and 28--34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35--44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' response of Dec. 8, 2003, is noted.

The claims in the application are claims 1-7, 15-23 and 28-44.

Claims 1-7, 15-23 and 28-34 stand withdrawn.

Claim 44 violates 35 U.S.C. 101 and 35 U.S.C. 112, since it is drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claim 44 is not a proper composition claim. A compound plus an inert carrier must be recited.

This is a 371 application. Content in a 371 application is controlled by 37 CFR 1.475. Once an allowable genus is arrived at, a method and a pharmaceutical composition claim will be added back in. We are not there yet. The heterocyclic expressions in claim 35 cannot be allowed.

Claim 42 is not allowable. Applicants have already picked a method of use as an anti-inflammatory. Applicants cannot have another method of use here. 37 CFR 1.475 make it clear that one method of use with be examined, at the appropriate time.

Claim 42 is in addition, obvious under 35 USC 103. The actual process of making a composition by mixing is old since the time of Alchemists working in caves.

This is a pharmaceutical. Variations in structure could easily affect result. The heterocyclic expressions in claim 35 are the type held unclear in In re Wiggins, 179 USPQ 421 at 423, which was cited with approval in In re Oetiker, 23 USPQ (2^{nd}) 1661 at 1662, 2^{nd} col.

Accordingly, claim 35 is rejected under 35 U.S.C. 112, 2^{nd} paragraph.

Adjacent O-S, O-O or S-S combinations are notoriously unstable.

A Markush listing of intended, conceived of, producible heterocyclic rings in what is needed here. It is not possible to classify and search the molecule, unless one knows exactly which heterocyclic ring is being claimed. The utility here is pharmaceutical. Declarations of unexpected results are often presented in this art. Applicant's breadth of heteroaryl and heterocyclic produce many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The specification is considered inadequate, here, to provide reasonable exemplification for the breath sought.

If it works, I claim it, is not a proper basis for claim. All claims examined are rejected under 35 U.S.C. 112, 1st and 2nd paragraph. Where are the heteroatoms located in the ring, and where is that supported in the specification with sufficient representative exemplification? Applicants rest too much conception with the reader, and do not back it up (the heterocyclic term indicated) with representative exemplification in the specification, demonstrated to work for applicant's purposes. Where is the demonstrated fact in return for a 17/ 20-year monopoly?

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role of the reader. Applicants should, in return for a 17/20-year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at 53.

The heterocyclic rings possible here is wide open to staggering possibilities.

Applicants place too much conception with the reader. The expression: "the heterocyclic ring" is open to any arrangement of heteroatoms.

Where are the starting materials in the specification? Any combination of 1 to 4 heteroatoms selected from N, O, or S is very high, especially in 9 membered rings.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the heteroatoms are: 1,2 or 1,3 or 1,4 and what they are , as each is a different ring with a different specific search.

These are compound claims; one must clearly know what is being claimed.

One, on reading the indication of heterocyclic, applied by applicant, has no idea where the heteroatoms are in this unknown ring.

Not all heterocyclic rings have been shown to be producible, as stable at room temperature. What is the source of the starting material? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic definition presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification? Even any combination of atoms, selected form the group consisting of O, S or N, rests specific conception with the reader. Not a fair burden in return for applicants receiving a 17;/20-year monopoly.

Claim 35 stands rejected under 35 U.S.C. 112, first paragraph, based on the enablement requirement of how to make the claimed invention. It is the position of the examiner that the specification fails to provide an adequate enabling disclosure as to the starting materials, where they would be obtained and what they are. There is no question here that access to the knowledge of the preparation of the starting materials is essential to making the composition. Cf. In re Hearth, 654, F2d 103, 210 USPQ 689 (CCPA 1981); Ex parte Moersch, 104 U.S.P.Q. 122 (Bd. App. 1954).

If it works, I claim it is not the proper basis for claim structure. Applicants should be setting forth specific demonstrated fact in return for a 17/20-year monopoly.

One (the reader) would have to conceive of the compound, and then make it, and then try it-to know whether it was included in applicant's invention. This is an undue burden. Applicants, in return for a 17/20-year monopoly, should be acting forth-demonstrated fact-not just ideas.

Inventor may only claim what is novel and non-obvious over prior art, and where invention overreaches and attempts to cover subject matter, which is properly in the public

domain, cost is ultimate finding of invalidity; in considering scope of claims, unclaimed features or advantages cannot be relied upon to limit that scope in attempt to impart patentability to claims, which embrace otherwise old or unpatentable subject matter. Specific embodiment that may be different from prior art is legally insufficient to prove patentability, since proper comparison is between prior art and claims. --Smith Industries Medical Systems Inc. v. Signs Inc. 45 U.S.P.Q.(2nd) 1512.

The specification cannot support (written description) the breadth sought. It would require undue experimentation to determine what is being claimed. The claim does not indicate exactly and clearly what compound is being claimed.

The claims measure the invention. United Carbon Co. vs. Binney & Smith Co. 55 U.S.P.Q. 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of claims held to this standard in Lockheed Aircraft Corp. vs. United States, 193 U.S.P.Q. 449, "Claims measure invention and resolution of Invention must be based on what is claimed.

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". We have consistently held that no applicant should have limitations of the specification read into claims where no express statement of the limitation is included in the claim": In re Priest 199 U.S.P.Q. 11, at 15.

The Commissioner puts out a New Letter to the Employees called PTO Pulse. The March 1998 issue on page 7 directs our attention to Gentry Gallery vs. Berkline

Corp. (CAFC) 45 U.S.P.Q. (2nd 1498). The CAFC invalidated certain broad claims for lack of written description under 35 U.S.C. 112, 1st paragraph.

Although applicant is generally allowed claims, when prior art permits, which cover more that specific embodiment shown, applicant cannot broaden claims to extent that they are effectively supporting disclosure, and narrow disclosure will, therefore, limit claim breadth.

The mere broad recitation of the term, again, in the specification, does not constitute support (description). Note In re Oetiker, 23 U.S.P.Q. (2nd) at 1662.

The Board looked to the specification for the necessary guidance. It found nothing that would reasonably apprise one skilled in the art as to the claims invention's scope, because the specification essentially uses the same words of degree as are used in the claims. While the specification discusses Oetiker's prior art claim structures, it does not indicate how the words of degree relate to or differ from such prior art, nor is any other definitional guidance given in the specification. The Board therefore correctly determined that the claims. When read in light of equivalents , define the scope of patent protection sought by Oetiker, and were indefinite within the meaning of section 112, second paragraph.

Oetiker argues that the terms and phrases found objection by the Board are acceptable in claim drafting. These "Broadening modifiers" are "standard tools" in claim drafting, Oetiker contends, are used "to avoid reliance on the doctrine of equivalents in infringement actions." This may well be true as a general proposition, but because the scope of the claims is unclear the rejection was proper. See In re Wiggins, 488 F2d

538, 541; 179 U.S.P.Q. 421, 423 (CCPA 1973). As to the multiple recitations of claim limitations and the instances of lack of antecedent basis, even if we accept Oetiker's arguments, we cannot say the Board erred in concluding that these portions of the claims were indefinite.

One, on reading the specification, cannot assume that applicants have the right to claim everything set forth within it. Much of the specification indicates the prior art, the background to the invention, the problem to be solved, and how applicant solved it.

Claims 36-~~44~~ are rejected as being dependent on a rejected claim. They could not be allowable without containing the rejected heterocyclic expressions of claim 35.

Heterocyclic is not just a substituent , it is a whole body of art larger than the 1,3 thiazine nucleus of claim 35.

What is the purpose the of the proviso at the end of claim 35. Is some art being written around?

JOHN M. FORD
PRIMARY EXAMINER
Group Art Unit 1624

Ford/LR
January 20, 2004